Operationalizing CTSU's Protocol and CIRB Update Listing for Processing Local Regulatory Documents

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Background:

Regulatory documents for studies overseen by the NCI CIRB must be processed and activated within 30 days of posting to the Clinical Trials Support Unit (CTSU) website. The University of Kansas Cancer Center (KUCC) Clinical Trials Office (CTO) regulatory team manages over 200 NCTN and ETCTN studies. Staying on top of the posts proved difficult for a smaller staff of four from 2015 to 2019. At the time of development, CTSU's Dashboard feature filtered to all CIRB-approved studies for the site, which made it difficult for coordinators to focus on only the subset of studies each coordinator managed. The manager of the regulatory team and one of the regulatory coordinators worked together to develop a better method to track and distribute these updates to individual coordinators.

Goals:

- Avoid missing important regulatory updates.
- Process amendments within 30 days of posting.

Solutions & Methods:

An Excel-savvy regulatory coordinator developed a smart spreadsheet to map protocol updates posted on CTSU to the studies maintained by the KUCC regulatory team.

The report is updated by our NCTN administrator. She exports both Protocol Updates and CIRB Updates from CTSU to Excel once a week (1). Only postings from the previous week are pasted into the mapping spreadsheet. The columns used are Date, Protocol ID, and Update description (2). In addition, the CTO's Research Systems team distributes two weekly reports (start-up and maintenance) of all CTO-managed studies from our Clinical Trial Master System (3). This report includes the Disease Working Group, Study Status, IRB number, Protocol ID, Principal Investigator, IRB Expiration Date, and Regulatory Contact. These reports are also pasted into the mapping spreadsheet (4).

Studies not managed by KUCC populate with an N/A and are filtered out of the report. The resulting report includes all updates posted to CTSU for the prior week for only those studies maintained by our regulatory coordinators (5). The NCTN administrator pastes the table into an email and distributes it to the regulatory coordinators, manager, and program director (6).

Outcomes:

Amendment processing timelines from CTSU posting to local activation improved from an average of 25.5 days to 11.9 days after implementation of the report. The team saw a high of 17 audit findings for delayed activation in 2017 to no regulatory audit findings in 2023.

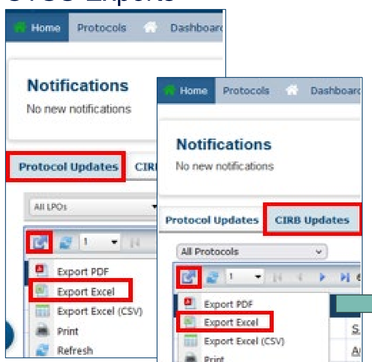
Lessons Learned & Future Directions:

A few errors have occurred since implementation, including new studies not being added to the Lookup mapping tab and typographical errors in Protocol IDs on the Lookup tab which made some studies show as N/A. This resulted in two instances of missed amendments.

In 2022, we implemented having each regulatory coordinator's functional manager review the report weekly to ensure items are processed within the 30-day window required for NCI CIRB studies. Staff are also instructed that the report is a second check and should not be the sole source of truth for protocol and CIRB updates on the studies they maintain.

While the CTSU Dashboard can now be filtered to a coordinator's selected studies, the weekly report allows for cross-coverage when coordinators are out and enables managers to track the work being completed on the team.

CTSU Exports



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CTSU

Protocol Updates

#	Date	Protocol	Update
1	21-Feb-2025	NHLBI-MDS	Memorandum: Notice of Sample Collection Discontinuation for the NHLBI-MDS Study
2	20-Feb-2025	NRG-BR008	Memorandum: Webinar Announcement
3	20-Feb-2025	NRG-HN014	Memorandum: Updated Biospecimen Collection and Submission Manual and Clarification for Sites Unable to Submit Biopsy Blocks
4	19-Feb-2025	A032102	Memorandum: PREDICT Informational Webinar
5	19-Feb-2025	10636	CTSU PROTOCOL ACTIVATION
6	18-Feb-2025	EA8171	Memorandum: Upcoming Study Closure
7	17-Feb-2025	S2308	Memorandum: SWOG Pharmacy Committee Task Force – Initial Order Build Focus Group

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CTMS Exports

DWG	Study Status	Study Number	Sponsor ID	PI	HSC Expiration Date	Regulatory Contact
Brain	Trial Status - Active/Enrolling					
Brain	Trial Status - Follow-up/Closed To Enrollment					
Brain	Trial Status - Follow-up/Closed To Enrollment					

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Mapping Spreadsheet

Map ID to Protocol:	DCP-001 Eligible	DWG	Study Status	Study Number	Sponsor ID	Principal Investigator	HSC Expiratic	Regulatory Contact
NRG-BN011	TRUE	Brain	Trial Status - Active/Enrolling					
N0577	TRUE	Brain	Trial Status - Follow-up/Closed To Enrollment					
NRG-BN010	FALSE	Brain	Trial Status - Follow-up/Closed To Enrollment					

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Date	Protocol	Update	DWG	STUDY_STATUS	HSC_NUMBER	SPONSORID	PRINCIPAL_INVESTIGATOR	HSC EXPIRATION DATE	Regulatory Contact
21-Feb-2025	NHLBI-MDS	Memorandum: Notice of Sample Collection Discontinuation for the NHLBI-MDS Study							
20-Feb-2025	NRG-BR008	Memorandum: Webinar Announcement	Breast RadOnc	Trial Status - Active/Enrolling					
20-Feb-2025	NRG-HN014	Memorandum: Updated Biospecimen Collection and Submission Manual and Clarification for Sites Unable to Submit Biopsy Blocks							
19-Feb-2025	A032102	Memorandum: PREDICT Informational Webinar	GU	Trial Status - Active/Enrolling					
19-Feb-2025	10636	CTSU PROTOCOL ACTIVATION							
18-Feb-2025	EA8171	Memorandum: Upcoming Study Closure	GU	Trial Status - Active/Enrolling					
17-Feb-2025	S2308	Memorandum: SWOG Pharmacy Committee Task Force – Initial Order Build Focus Group	Lymphoma/Myeloma	Trial Status - Active/Enrolling					

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Email Distribution

Protocol Report Week Ending 02/17/2025

Reply | Reply All | Forward

Tue 2/18/2025 9:47 AM

You replied to this message on 2/21/2025 1:05 PM.

Date	Protocol	Update	DWG	STUDY_STATUS	HSC_NUMBER	SPONSORID	PRINCIPAL_INVESTIGATOR	HSC EXPIRATION DATE	Regulatory Contact
17-Feb-2025	MM1YA-S01	Memorandum: Updated Master Forms Set	Leukemia/Myeloid	Trial Status - Active/Enrolling					
13-Feb-2025	EA9181	Memorandum: Laboratories President's Day: Schedule 2025	Leukemia/Myeloid	Trial Status - Active/Enrolling					
13-Feb-2025	10186	Amendment #15: Change Memo for Protocol (PVD 01/27/25)	Brain Multiple RadOnc	Trial Status - Active/Enrolling					
13-Feb-2025	10186	Protocol Version Date 01/27/25	Brain Multiple RadOnc	Trial Status - Active/Enrolling					
17-Feb-2025	S1800D	Protocol Version Date 10/24/24 Distribution of Pembrolizumab Action Letter and Potential Unanticipated Problem	Lung	Trial Status - Follow-up/Closed To Enrollment					